

### **REMARKS**

Claims 1-16, and 18-28 are pending in the application. Claim 17 is canceled without prejudice to the subject matter therein. Claims 20-24 have been withdrawn from consideration without prejudice to the subject matter therein. Dependent claims 7, 9, 12, 13, and 19 have been rewritten in independent form. Claims 1-16, 18-19, and 25-28 stand rejected.

#### **35 USC §112 Rejection, 2<sup>nd</sup> paragraph**

Claims 14 and 15 were rejected under §112, 2<sup>nd</sup> paragraph, as being allegedly indefinite because it was “not clear to [the] Examiner how the rotation of the drum can act to tumble the implants if the implants are maintained in an aloft position within the drum.” In response the undersigned submits that this interpretation is erroneous as it adds limitations to the claims not provided therein. One underlying premise of this rejection is that the compressible fluid system is activated the entire time during which a medical implant is within the drum. In other words, under the Office action’s interpretation the claims require that the suspension system be activated before, during, and after, the rotation of the drum has begun. That is, however, too narrow of an interpretation. Claim 14, for instance, simply recites that a fluid suspension system is provided and that this system can force compressible fluid into the drum. The claim does not require that the compressible fluid system be operating the entire time the drum is rotating. For example, an infringing suspension system could be periodically turned off and on, operated only after a device tumbles away from the drum. Under this reading of the claim, as well as the other lawful readings, the claims are not indefinite. Reconsideration is, therefore, requested.

#### **35 USC §102(e) Rejections**

Claims 1-4 and 25-28 are rejected under 35 USC §102(e) as being allegedly anticipated by US Pat. No. 6,368,658 by Schwarz et al. (“Schwarz ‘658”).

As to claim 1, the undersigned submits that it is patentable over Schwarz ‘658 at least because claim 1 recites “tumbling the medical implant by rotating the drum.” The Office action concedes this shortcoming, but then attempts to remedy it by arguing that the chamber 120 in Schwarz ‘658 “is inherently capable of being rotated.” This presumption is flawed as

the chamber 120 in Schwarz '658 contains an external fluid supply 140. *See* figs. 1-3. Thus, the Office action's reading of Schwarz '658 ignores a direct structure of Schwarz that contravenes the Office action's presumptions as to what Schwarz inherently discloses. For at least this reason, the undersigned submits that claim 1, and claims 2-4, and 29, are patentable over Schwarz '658.

As to claim 25, consistent with the above discussion, as Schwarz '658 does not disclose a "pan coater including a drum rotatable about a longitudinal axis having a wall and a bottom, the wall having a plurality of orifices," the undersigned submits that claims 25 and 26-28 are patentable over Schwarz '658 as well.

### **35 U.S.C. §103(a) Rejections**

The section 103 rejections are addressed in seriatim.

Claims 5-16, and 18-19 stand rejected under 35 USC §103(a) as being allegedly unpatentable over U.S. Pat. No. 6,607,598 by Schwarz et al. ("Schwarz '598") in view of U.S. Pat. No. 4,581,242 by Forster ("Forster"). The undersigned submits that neither of the cited references disclose a "drum containing a plurality of orifices in the wall," as recited in claim 5. For at least this reason, the undersigned submits that claim 5, and hence dependent claims 6, 8, 14-16, 18 are patentable over the cited references.

As to claims 7 and 12, the undersigned submits that the cited references do not at least disclose a "drum containing a plurality of orifices in the wall," as recited in claims 7 and 12.

As to claims 9, 10-11, and 13, the undersigned submits that the cited references do not at least disclose a "drum containing a plurality of orifices in the wall," as recited in claim 9 and 13. For at least this reason, the undersigned submits that claim 9, and hence claims 10-11 and 13, are patentable over the cited references.

In addition, the undersigned submits that Schwarz '598 does not disclose "heating the rotatable drum after spraying the therapeutic into the drum," as recited by claim 13. The Office action asserts that "Schwarz teaches a coating operation temperature of 0-200 °C (col.

10, line 8), which would meet the limitation of heating the drum before, during, and *after* spraying of the therapeutic agent to maintain such a temperature.” However, the cited portion of Schwarz ‘598 regards controlling “processing parameters such as the fluidization air composition, temperature and humidity *when coating* with drugs or polymers.” Thus, this cited portion does not regard transferring heat into or at the drum after spraying as recited in the claim. For at least this reason, the undersigned submits that claim 13 is patentable over the cited references.

As to claim 19, the undersigned submits that the references cited do not at least disclose a “drum containing a plurality of orifices in the wall,” as recited in claim 19. For at least this reason, the undersigned submits that claim 19 is patentable over the cited references.


The undersigned traverses the assertions made in the Office action directed to claim 19. There, the Office action explains that “[i]n a spray coating operation, a large quantity of coating material is ‘lost’ and misses its targets. It is Examiner’s position that one of ordinary skill in the art would provide a recycling operation to recover the lost pharmaceuticals to be used in a later coating operation so as to maximize manufacturing profits.” The undersigned submits that the cited references are silent on all of these issues and, therefore, submits that this entire discussion and analysis is erroneous and may not be properly relied upon unless citations to specific prior art references are provided.

**CONCLUSION**

In view of the foregoing, the Applicants respectfully submit that the application is now in condition for allowance. Should the Examiner have any questions concerning this application, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

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